

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of:

Munro et al.

Serial No.: 10/530,087

Filed: January 30, 2006

For: DEVICE FOR BONE FIXATION

Group Art Unit: 3733

Examiner: Nicholas W. Woodall

Board of Patent Appeals and Interferences

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REPLY BRIEF UNDER 37 C.F.R. § 41.41

In response to the Examiner's Answer mailed on May 23, 2008 to the revised Appeal Brief filed March 26, 2008, and pursuant to 37 C.F.R. § 41.41, Appellants present this Reply Brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 1 and 4 - 21 in the Final Office Action dated September 17, 2007. The appealed claims are set forth in the attached Claims Appendix.

1. Status of the Claims

Claims 1 and 4 - 21 stand rejected in the Final Office Action. The final rejection of claims 1 and 4 - 21 is being appealed.

2. Grounds of Rejection to be Reviewed on Appeal

- I. Whether claims 1, 7, 9, 13 and 21 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Chemello (U.S. Patent No. 6,077,264).
- II. Whether claims 6 and 16 are unpatentable under 35 U.S.C. § 103(a) as obvious over Chemello.
- III. Whether claims 1, 4 - 8, 13 and 16 are unpatentable under 35 U.S.C. § 103(a) as obvious over Stedtfeld (Patent No. DE 198 29 228 C1) in view of Chemello.
- IV. Whether claim 14 is unpatentable under 35 U.S.C. § 103(a) as obvious over Stedtfeld in view of Chemello in further view of Pennig (U.S. Patent No. 5,356,413).
- V. Whether claim 18 is unpatentable under 35 U.S.C. § 103(a) as obvious over Stedtfeld in view of Chemello in further view of Seidel (U.S. Patent No. 4,858,602).
- VI. Whether claims 17, 19 and 20 are unpatentable under 35 U.S.C. § 103(a) as obvious over Stedtfeld in view of Chemello in further view of Pennig.
- VII. Whether claims 1, 9, 11 and 12 are unpatentable under 35 U.S.C. § 103(a) as obvious over Aginsky (U.S. Patent No. 4,227,518) in view of Chemello.

3. Argument

- I. The Rejection of Claims 1, 7, 9, 13 and 21 Under 35 U.S.C. § 102(b) as Anticipated by Chemello Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 1, 7, 9, 13 and 21 were rejected under 35 U.S.C. 102(b) as anticipated by Chemello. (See 9/17/07 Office Action, pp. 2 - 3). In support of the rejection, the Examiner stated that Chemello teaches all of the limitations of claim 1, not referencing any particular elements of Chemello therein. (*Id.*). The Examiner further stated that the limitation of an angular tab in claim 1 is a functional limitation and accordingly, that

Chemello need only disclose a structural element capable of performing the function of the angled tab. (See 12/3/07 Advisory Action, p. 2).

B. Chemello Does Not Show or Suggest an Angled
Tab as Recited in Claim 1

It is respectfully submitted that Chemello fails to teach or suggest “an angled tab configured and dimensioned to have a center of gravity lying on a radius of a cross-sectional area of the intramedullary pin taken orthogonally to the intramedullary pin's longitudinal axis and enclosing an angle β relative to a plane defined by the transverse borehole axis and the intramedullary pin's longitudinal axis, where angle β is between 0° and $+100^\circ$ or between 0° and -100° ,” as recited in claim 1.

Initially, the Examiner has indicated that the recited limitation is a functional limitation and that Chemello is capable of performing the recited function. (See 5/23/08 Examiner's Answer, p. 11). However, it is respectfully submitted that the above recited limitation is not a functional limitation but rather, a structural limitation intended to define the architecture of the angled tab. Specifically, the “angled tab” of claim 1 must be formed of a size and shape that permits a center of gravity thereof to lie within an angle β of the transverse borehole axis (i.e., the center of gravity must fall on a select portion of the angled tab so that when placed over the greater trochanter, the center of gravity lies within $\pm 100^\circ$ of the transverse borehole axis). Were the angled tab structured differently, the center of gravity would fall out of the desired β range. For example, if an oblong shape is employed for the tab, the center of gravity may fall along a side wall thereof outside of a range of angle β as defined in claim 1. It is therefore submitted that the mere positioning of the angled tab cannot solely meet the recited limitation.

It is therefore respectfully submitted that claim 1 does not recite any functional limitations and the Examiner's argument that Chemello only needs to be capable of performing the functions of claim 1 is invalid. It is submitted that claim 1 and its dependent claims 7, 9 and 13 are allowable over Chemello for at least this reason.

Furthermore, it is noted that the Chemello not only does not meet the limitations of claim 1, but is also incapable of being modified to overcome these limitations. Specifically, Chemello fails to teach or suggest "a bone plate disposed at the proximal end of the intramedullary pin, the bone plate having a length extending toward the distal tip of the intramedullary pin and adapted to lie in contact with the greater trochanter," as recited in claim 1. Chemello makes no disclosure in this regard and rather, teaches only that the lip 91 connected at a proximal end to the screw 2, lies over the bone 8, making no reference to the location of the lip 91 relative to the greater trochanter. (See Chemello, col. 4, ll. 4 - 22). The drawings of Chemello, however, clearly indicate that the lip 91 is formed to lie over a portion of the bone abutting the intertrochanteric line of the thigh bone. (See Chemello, Figs. 2, 4a, 4). Specifically, the embodiments of Figs. 4a and 4, which show the anterior surface of the right femur, clearly depict the lip 91 seated over a portion of the anterior surface, spaced apart from the greater trochanter on the lateral wall of the bone. As further shown in the lateral view of Fig. 2 of Chemello, the nail object of Chemello juts out of the bone at a position below the greater trochanter and is therefore incapable of "[lying] in contact with the greater trochanter," as recited in claim 1. It is respectfully submitted that the 102(b) rejection of claim 1 is therefore not allowable for at least this additional reason.

The Examiner has indicated that the lip 91 of Chemello is capable of contacting the greater trochanter. (See 5/23/08 Examiner's Answer, p. 11). However, it is respectfully submitted that the Examiner provides no motivation, except to overcome the limitations of claim 1, to make this assertion. Rather, it is respectfully submitted that Chemello actually teaches away from a nail object with a lip 91 made to "lie in contact with the greater trochanter," as recited in claim 1. Specifically, the Chemello device is directed to "a nail that can be easily removed from the bone inner cavity when this is necessary for any reason whatsoever." (See Chemello, col. 1, ll. 51 - 53). Accordingly, Chemello notes that the nail object is to reside within the bone inner cavity (i.e., the medullary cavity) which is housed in the shaft of the femur between the two epiphyses of the femur, as known to those skilled in the art. It is for this reason that Chemello designs the nail object to project out of the femur from an end portion of the medullary cavity, as shown in Fig. 2. It is submitted that modifying the Chemello device so that the nail object contacts the greater trochanter at a proximal end would be detrimental to the functioning of the device as it would reduce the ease of removal of the nail from "the bone inner cavity" by forcing the nail object into an additional layer of the bone (i.e., the spongy bone of the epiphysis) which would

only complicate removal from the bone, as would be understood by those skilled in the art.

It is therefore respectfully submitted that Chemello fails to teach or suggest a "a bone plate disposed at the proximal end of the intramedullary pin, the bone plate having a length extending toward the distal tip of the intramedullary pin and adapted to lie in contact with the greater trochanter," as recited in claim 1 and rather, teaches away from this limitation. Still further, it is submitted that there would have been no motivation to have modified the Chemello device to meet the aforementioned limitation. Specifically, it is noted that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. (*See In re Kahn*, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006)). It is submitted that one skilled in the art would not have been motivated to modify the Chemello device to place the lip 91 in contact with the greater trochanter, as doing so would provide no benefit thereto and would undermine a goal of the invention -- i.e., facilitating removal nail from the bone.

For these additional reasons, it is submitted that Chemello fails to teach or suggest the limitations of claim 1. Because claims 7, 9 and 13 depend from, and therefore include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Claim 21 recites limitations substantially similar to those of claim 1 including a bone fixation device comprising "an intramedullary pin having a longitudinal axis, a proximal end, and a distal tip configured and dimensioned for insertion into a medullary canal of a bone, the intramedullary pin having a total length with proximal and distal halves, and the proximal half of the intramedullary pin includes at least one borehole passing through the intramedullary pin transverse to the longitudinal axis, the at least one borehole defining a transverse borehole axis; a bone plate disposed at the proximal end of the intramedullary pin, *the bone plate having a length extending toward the distal tip of the intramedullary pin and adapted to lie in contact with the greater trochanter*; wherein the length of the plate ends proximally above the borehole in the intramedullary pin; and wherein the bone plate includes *an angled tab with a center of gravity, the angled tab configured and dimensioned such that a first plane defined by the center of gravity and the longitudinal axis intersects a second plane defined by the transverse borehole axis and the longitudinal axis at an angle β of between 0° and +100° degrees.*" (Emphasis

Added). It is therefore submitted that claim 21 is allowable for at least the same reasons noted above with regard to claim 1.

II. The Rejection of Claims 6 and 16 Under 35 U.S.C. § 103(a) as Obvious over Chemello Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 6 and 16 were rejected under 35 U.S.C. 103(a) as unpatentable over Chemello. (See 9/17/07 Office Action, p. 4).

B. Chemello Does not Show or Suggest an Angled Tab as Recited in Claim 1

Claim 1 has been recited above and discussed with reference to the 35 U.S.C. § 102(b) rejection under Chemello. Claims 6 and 16 depend from and therefore include all the limitations of independent claim 1. As discussed above, Chemello fails to teach or suggest "a bone plate disposed at the proximal end of the intramedullary pin, the bone plate having a length extending toward the distal tip of the intramedullary pin and adapted to lie in contact with the greater trochanter" or "an angled tab configured and dimensioned to have a center of gravity lying on a radius of a cross-sectional area of the intramedullary pin taken orthogonally to the intramedullary pin's longitudinal axis and enclosing an angle β relative to a plane defined by the transverse borehole axis and the intramedullary pin's longitudinal axis, where angle β is between 0° and +100° or between 0° and -100," as recited in claim 1. As also noted above, modifying the Chemello device to overcome these limitations is not allowable. Accordingly, because claims 6 and 16 depend from and, therefore, include all of the limitations of independent claim 1, it is respectfully submitted that these claims are also allowable for the same reasons. Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 103(a) of claims 6 and 16.

III. The Rejection of Claims 1, 4 - 8, 13 and 16 Under 35 U.S.C. § 103(a) as Obvious over Stedtfeld in view of Chemello Should be Reversed.

A. The Examiner's Rejection

In the Final Office Action, claims 1, 4 - 8, 13 and 16 were rejected under 35 U.S.C. 103(a) as obvious over Stedtfeld in view of Chemello. (See 9/17/07 Office Action, pp. 4 - 7).

The Examiner stated that Stedtfeld discloses the device as claimed but fails to disclose a bone plate attached to the proximal end of the intramedullary pin. The Examiner references Chemello to overcome this deficiency. (*Id.*) In the Advisory Action dated 12/3/07, however, the Examiner states that “Chemello is not being used to teach the bone plate” and that “[t]he examiner believes that Stedtfeld discloses a bone plate capable of performing the functional limitations of the claims.” (*See* 12/3/07 Advisory Action, p. 2).

B. Stedtfeld and Chemello Do not Disclose or Suggest
an Angled Tab or Bone Plate as Recited in Claim 1

It is submitted that the Examiner is correct in stating that Stedtfeld fails to disclose a bone plate attached to the proximal end of the intramedullary element much less “an angled tab configured and dimensioned to have a center of gravity lying on a radius of a cross-sectional area of the intramedullary pin taken orthogonally to the intramedullary pin’s longitudinal axis and enclosing an angle β relative to a plane defined by the transverse borehole axis and the intramedullary pin’s longitudinal axis, where angle β is between 0° and $+100^\circ$ or between 0° and -100° ,” as recited in claim 1. However, as noted above with regard to the 35 U.S.C. § 102(b) rejection, Chemello also fails to cure this deficiency. Accordingly, it is submitted that Stedtfeld and Chemello, taken either alone or in combination, neither teach nor suggest “a bone plate disposed at the proximal end of the intramedullary pin, the bone plate having a length extending toward the distal tip of the intramedullary pin and adapted to lie in contact with the greater trochanter” or “an angled tab configured and dimensioned to have a center of gravity lying on a radius of a cross-sectional area of the intramedullary pin taken orthogonally to the intramedullary pin’s longitudinal axis and enclosing an angle β relative to a plane defined by the transverse borehole axis and the intramedullary pin’s longitudinal axis, where angle β is between 0° and $+100^\circ$ or between 0° and -100° ,” as recited in claim 1. Accordingly, it is respectfully submitted that claim 1 is allowable over Stedtfeld and Chemello taken either alone or separately for the same reasons stated above in regard to the anticipation rejection. Since claims 4 - 8, 13 and 16 depend from and therefore include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

IV. The Rejection of Claim 14 Under 35 U.S.C. § 103(a) as Obvious over Stedtfeld in view of Chemello in further view of Pennig Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claim 14 was rejected under 35 U.S.C. 103(a) as obvious over Stedtfeld in view of Chemello in further view of Pennig. (See 9/17/07 Office Action, p. 7).

B. Neither Stedtfeld nor Chemello nor Pennig Discloses or Suggests an Angled Tab or a Bone Plate as Recited in Claim 1

Claim 1 has been recited above and discussed with reference to the 35 U.S.C. § 103(a) rejection under Stedtfeld and Chemello. Claim 14 depends from and therefore includes all the limitations of independent claim 1. As discussed above, Stedtfeld and Chemello do not teach or suggest the limitations of independent claim 1 and claim 1 is therefore allowable over Stedtfeld and Chemello, either alone or in combination. Pennig does not cure the deficiencies of Stedtfeld and Chemello noted above. Accordingly, it is respectfully submitted that claim 14 is allowable for the same reasons stated in regard to claim 1.

V. The Rejection of Claim 18 Under 35 U.S.C. § 103(a) as Obvious over Stedtfeld in view of Chemello in further view of Seidel Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claim 18 was rejected under 35 U.S.C. 103(a) as obvious over Stedtfeld in view of Chemello in further view of Seidel. (See 9/17/07 Office Action, pp. 7 - 8).

B. Neither Stedtfeld nor Chemello nor Seidel Discloses or Suggests an Angled Tab or a Bone Plate as Recited in Claim 18

Claim 18 recites limitations substantially similar to those of claim 1, including "a bone plate disposed at the proximal end of the intramedullary pin, the bone plate including an angled tab with a pair of petals extending toward the distal end of the intramedullary pin and adapted to

lie in contact with the greater trochanter” and an angled tab “configured and dimensioned to have a center of gravity lying on a radius of a cross-sectional area of the intramedullary pin taken orthogonally to the intramedullary pin’s longitudinal axis and enclosing an angle β relative to a plane defined by the transverse borehole axis and the intramedullary pin’s longitudinal axis, where angle β is between 0° and $+100^\circ$ or between 0° and -100° .” Accordingly, it is submitted that Stedtfeld and Chemello fail to show or suggest the recited arrangement. It is further submitted that Seidel fails to cure the above noted deficiencies of Chemello and Stedtfeld and that claim 18 is allowable for the same reasons noted above in regard to claim 1.

VI. The Rejection of Claims 17, 19 and 20 Under 35 U.S.C. § 103(a) as Obvious over Stedtfeld in view of Chemello in further view of Seidel in further view of Pennig Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 17, 19 and 20 were rejected under 35 U.S.C. 103(a) as obvious over Stedtfeld in view of Chemello in further view of Seidel in further view of Pennig. (See 9/17/07 Office Action, p. 8).

B. Neither Stedtfeld, Chemello, Seidel nor Pennig Discloses or Suggests either an Angled Tab or a Bone Plate as Recited in Claims 1 and 18

Claims 1 and 18 have been recited above and discussed with reference to the 35 U.S.C. § 103(a) rejection under Stedtfeld and Chemello. Claim 17 and 19 - 20 depend from and therefore includes all the limitations of independent claims 1 and 18. As discussed above, Stedtfeld and Chemello do not teach or suggest the limitations of independent claim 1 and claim 1 is therefore allowable over Stedtfeld and Chemello, either alone or in combination. Seidel and Pennig do not cure the deficiencies of Stedtfeld and Chemello noted above. Accordingly, it is respectfully submitted that claims 1 and 18 are allowable over Stedtfeld, Chemello, Seidel and Pennig. It is therefore submitted that claims 17 and 19 - 20 are allowable for the same reasons stated in regard to claims 1 and 18.

VII. The Rejection of Claims 1, 9, 11 and 12 as Obvious over Aginsky
in view of Chemello Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 1, 9, 11 and 12 were rejected under 35 U.S.C. 103(a) as obvious over Aginsky in view of Chemello. (See 9/17/07 Office Action, pp. 8 - 10).

B. Neither Aginsky nor Chemello Discloses or
Suggests Either an Angled Tab or a Bone Plate as
Recited in Claim 1

Aginsky purports to show a nail with a tubular sheath intended to be traversed therethrough a fractured thigh-bone. (See Aginsky, col. 3, ll. 41 - 56). Aginsky fails to teach or suggest "a bone plate disposed at the proximal end of the intramedullary pin, the bone plate having a length extending toward the distal tip of the intramedullary pin and adapted to lie in contact with the greater trochanter; wherein the length of the plate ends proximally above the borehole in the intramedullary pin; and wherein the bone plate includes an angled tab configured and dimensioned to have a center of gravity lying on a radius of a cross-sectional area of the intramedullary pin taken orthogonally to the intramedullary pin's longitudinal axis and enclosing an angle β relative to a plane defined by the transverse borehole axis and the intramedullary pin's longitudinal axis, where angle β is between 0° and $+100^\circ$ or between 0° and -100° ", as recited in claim 1. The Examiner asserts that this deficiency is cured by Chemello. However, as described above, Chemello neither shows nor suggests these claim limitations and Aginsky fails to cure this deficiency and, for at least this reason, it is respectfully submitted that claim 1 is allowable over Chemello and Aginsky taken either alone or in combination. Since claims 9, 11 and 12 depend from and therefore include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

8. Conclusion

For the reasons set forth above, Appellants respectfully request that the Board reverse the final rejections of the claims by the Examiner and indicate that claims 1 and 4 - 21 are allowable.

Respectfully submitted,

Date:

7/23/08



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CLAIMS APPENDIX

1. (Previously Presented) A bone fixation device comprising:

an intramedullary pin having a longitudinal axis, a proximal end, and a distal tip configured and dimensioned for insertion into a medullary canal of a bone, the intramedullary pin having a total length with proximal and distal halves, and the proximal half of the intramedullary pin includes at least one borehole passing through the intramedullary pin transverse to the longitudinal axis, the at least one borehole defining a transverse borehole axis;

a bone plate disposed at the proximal end of the intramedullary pin, the bone plate having a length extending toward the distal tip of the intramedullary pin and adapted to lie in contact with the greater trochanter;

wherein the length of the plate ends proximally above the borehole in the intramedullary pin; and

wherein the bone plate includes an angled tab configured and dimensioned to have a center of gravity lying on a radius of a cross-sectional area of the intramedullary pin taken orthogonally to the intramedullary pin's longitudinal axis and enclosing an angle β relative to a plane defined by the transverse borehole axis and the intramedullary pin's longitudinal axis, where angle β is between 0° and $+100^\circ$ or between 0° and -100° .

2. (Canceled).

3. (Canceled).

4. (Previously Presented) The device of claim 1, wherein the distal half of the intramedullary pin further includes a transverse borehole passing through it for accommodating a locking screw.

5. (Previously Presented) The device of claim 1, wherein the intramedullary pin, is provided with at least two transverse grooves in its distal half .

6. (Previously Presented) The device of claim 1, wherein the bone plate and the intramedullary pin are a single piece.
7. (Previously Presented) The device of claim 1, wherein angle β is between $+40^\circ$ and $+50^\circ$.
8. (Previously Presented) The device of claim 1, wherein the proximal half of the intramedullary pin has a second transverse borehole, which passes through it for accommodating a second hip screw.
9. (Previously Presented) The device of claim 1, wherein the bone plate has a circular borehole and the proximal rear end of the intramedullary pin has a cylindrical elevation corresponding thereto, so that the bone plate may be disposed about this elevation.
10. (Previously Presented) The device of claim 1, wherein the bone plate has a cam, which can be lowered into a depression, provided at the proximal end at the intramedullary pin, so that the bone plate can be connected with the intramedullary pin in a defined relative position and secured against rotation.
11. (Previously Presented) The device of claim 9, wherein the cylindrical elevation at the proximal end of the intramedullary pin has an external thread.
12. (Previously Presented) The device of claim 11, further comprising a nut with an internal thread corresponding to the external thread.
13. (Previously Presented) The device of claim 1, wherein the tab, viewed parallel to the longitudinal axis, extends around the intramedullary pin at an angle α , the angle α being between 10° and 200° .
14. (Previously Presented) The device of claim 1, wherein the bone plate has at least one perforation.
15. (Previously Presented) The device of claim 10, wherein the cylindrical elevation at the

proximal rear end of the intramedullary pin has an external thread.

16. (Previously Presented) The device of claim 1, wherein angle β is between -40° and -50° .

17. (Previously Presented) The device of claim 1, wherein the bone plate includes a pair of petals having at least two perforations.

18. (Previously Presented) A bone fixation device comprising:

an intramedullary pin having a longitudinal axis, a proximal end, and a distal end configured and dimensioned for insertion into a medullary canal of a bone, the intramedullary pin having a total length with proximal and distal halves, the proximal half of the intramedullary pin including at least one borehole passing through the intramedullary pin transverse to the longitudinal axis, the at least one borehole defining a transverse borehole axis;

a bone plate disposed at the proximal end of the intramedullary pin, the bone plate including an angled tab with a pair of petals extending toward the distal end of the intramedullary pin and adapted to lie in contact with the greater trochanter;

wherein the angled tab does not extend past the borehole in the intramedullary pin; and wherein the angled tab is configured and dimensioned to have a center of gravity lying on a radius of a cross-sectional area of the intramedullary pin taken orthogonally to the intramedullary pin's longitudinal axis and enclosing an angle β relative to a plane defined by the transverse borehole axis and the intramedullary pin's longitudinal axis, where angle β is between 0° and $+100^\circ$ or between 0° and -100° .

19. (Previously Presented) The device of claim 18, wherein the angled tab includes a plurality of perforations.

20. (Previously Presented) The device of claim 18, wherein the angled tab extends around the intramedullary pin over an angle of between 10° and 200° relative to the longitudinal axis.

21. (Previously Presented) A bone fixation device comprising:

an intramedullary pin having a longitudinal axis, a proximal end, and a distal tip configured and dimensioned for insertion into a medullary canal of a bone, the intramedullary pin having a total length with proximal and distal halves, and the proximal half of the intramedullary pin includes at least one borehole passing through the intramedullary pin transverse to the longitudinal axis, the at least one borehole defining a transverse borehole axis;

a bone plate disposed at the proximal end of the intramedullary pin, the bone plate having a length extending toward the distal tip of the intramedullary pin and adapted to lie in contact with the greater trochanter;

wherein the length of the plate ends proximally above the borehole in the intramedullary pin; and

wherein the bone plate includes an angled tab with a center of gravity, the angled tab configured and dimensioned such that a first plane defined by the center of gravity and the longitudinal axis intersects a second plane defined by the transverse borehole axis and the longitudinal axis at an angle β of between 0° and $+100^\circ$ degrees.